OCT 1 9 2000

K 003225

510(K) SUMMARY

Submitted by:

Mary Ellen Snyder
Sr. Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Proposed Device:

Solution Administration Sets with Capless Luer Activated Valve.

Predicate Device:

Solution Administration Sets with Capped Luer Activated Valve, cleared under premarket notification K974571, May 21, 1998.

Device Description and Statement of Intended Use:

The modification, which is the subject of this Special 510(k), is substitution of the current NP Medical capped LAV with the NP Medical capless LAV in Baxter solution administration sets. The NP Medical capless LAV to be incorporated into Baxter sets is covered by K973916, NP Medical Capless Luer Activated Valve, cleared March 9, 1998. All other aspects of the set design remain unchanged.

Baxter Solution Administration Sets with Capless Luer Activated Valve are intended for use with a vascular access device for the administration of drugs and solutions. The capless LAV is an in-line injection site which can be connected to standard male luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluids. This is the **same intended use** as previously cleared for the currently marketed Solution Administration Sets with Capped Luer Activated Valve.

Summary of Technological Characteristics of New Device to Predicate Device

The technological characteristics of Solution Administration Sets with Capless Luer Activated Valve do not differ significantly from the currently marketed Solution Administration Sets with Capped Luer Activated Valve. The devices utilize the same fundamental scientific technology and have the same intended use.

Discussion of Non-Clinical Tests; Conclusions Drawn from Nonclinical Tests

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2000

Ms. Mary Ellen Snyder
Senior Manger of Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K003225
Trade Name: Solution Administration Sets With Capped Luer Activated Valve
Regulatory Class: II and II
Product Code: FPA and FMF
Dated: October 13, 2000
Received: October 16, 2000

Dear Ms. Snyder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K00 3225

Device Trade Name: Baxter Solution Administration Sets with Capless Luer Activated Valve

Indication for Use: Baxter Solution Administration Sets with Capless Luer Activated Valve are intended for use with a vascular access device for the administration of drugs and solutions. The capless LAV is an in-line injection site which can be connected to standard male luer adapters (e.g., syringes or sets) for continuous or intermittent fluid administration or the withdrawal of fluids.

Patricia Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K00 3225